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10/552,136

10/06/2005

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EXAMINER

BROOKS, JULIAN D

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/552,136 | Applicant(s) NAKASHIMA ET AL. | |
| | Examiner JULIAN D. BROOKS | Art Unit 2624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/06/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-20 are pending in this application.
2. Examiner acknowledges applicant's preliminary amendments "**PRELIMINARY AMENDMENT**" filed 10/06/2005, amending claims 7, 9, 17, and 19.
3. Examiner acknowledges applicant's preliminary amendments "**PRELIMINARY AMENDMENT**" filed 07/10/2006, amending the specification.

Priority

4. Acknowledgment is made that this application is a national stage filing under 35 U.S.C. 371 of international application no. PCT/JP04/04993 filed on **04/07/2004**.
5. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) based on Japanese Patent Application Nos. 2003-103677, filed on **04/08/2003** and 2003-194954, filed on 07/10/2003. The certified copy received with this Application No. **10/552136**, filed on **10/06/2005**.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on 10/06/05 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered and a copy is enclosed within this office action.

Drawings

7. The drawings filed on 10/06/2005 are approved for examination purposes.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-4, 6, 9-14, 16, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sabol et al., U.S. Patent Publication No. 2004/ 0101086 A1, filed on 10/27/2002, and further in view of Kim et al., U.S. Patent No. 6278761, published on 08/21/2001.

With respect to claim 1, Sabol discloses "A medical image diagnosing support apparatus" (See Figures 1 & 2)

"comprising: a first extraction means which extracts a body region of a subject from a tomographic image of the subject acquired by a medical tomographic apparatus" (Page 4, Paragraphs 0040, 0043, & 0044, Page 5, Paragraph 0046, lines 1-2, and see

Figure 5, extraction means corresponds to Sabol's computer for tissue characterization);

"a second extraction means which extracts a non-adipose region from the body region" (Page 5, Paragraph 0046, lines 2-7, non-adipose region corresponds to Sabol's organ such as the liver);

"a third extraction means which extracts a total body adipose region from the body region" (Page 5, Paragraph 0046, lines 7-11, total body adipose region corresponds to Sabol's fatty tissue);

"a display control means which controls of displaying the tomographic image on an image display device" (Page 3, Paragraph 0031, and Page 5, Paragraph 0046, lines 11-23)

It is however noted that Sabol fails to explicitly disclose "a separation means which separates the total body adipose region into a visceral adipose region and a subcutaneous adipose region based on positional information of the non-adipose region"; and

"with clear indication of the visceral adipose region and the subcutaneous adipose region", as claimed.

On the other hand Kim teaches "a separation means which separates the total body adipose region into a visceral adipose region and a subcutaneous adipose region based on positional information of the non-adipose region" (Col. 3, lines 15-31, visceral and subcutaneous adipose regions correspond to Kim's intra-abdominal cavity fat and subcutaneous fat respectively), and

“with clear indication of the visceral adipose region and the subcutaneous adipose region” (Col. 3, lines 18-38, clear indication corresponds to Sabol’s high contrast image).

It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to incorporate the teachings of Kim into the apparatus for quantifying tissue fat content of Sabol because both Kim and Sabol are directed to medical image specifically for viewing body tissue (Sabol: abstract; and Kim: Col. 2, lines 10-23), more particularly both are directed segmenting and distinguishing between the types of imaged body tissue (Sabol: Page 1, Paragraph 0008, also see Figures 5 & 6; and Kim: Abstract) and both are in the same field of endeavor.

Furthermore, incorporate the teachings of Kim into Sabol would have allowed users of Sabol’s multi-energy computed tomography system to not only produce an image distinguishing lean and fat tissue (Sabol: Page 1, Paragraph 0007-0008), but also particularly further segment the imaged fat tissue into subcutaneous and intra-abdominal areas as suggested by Kim (Kim: abstract).

Therefore, combination of Sabol and Kim, prior art would have been obvious to one of ordinary skill in the art at the time of invention because to apply the segmentation of subcutaneous and intra-abdominal fat tissue of as taught by Kim, to improve the quantifying fat tissue content CT system as disclosed by Sabol would have yielded the predictable result of improving diagnostic ability by determining and analyzing a subcutaneous to intra-abdominal fat ratio as suggested by Kim (Kim: Page 1, lines 38-46).

With respect to claim 2, Sabol as modified by Kim teaches “wherein the second extraction means extracts the non-adipose region by performing threshold processing of a pixel value in the tomographic image” (Page 4, Paragraph 0045, threshold processing corresponds to Sabol’s Hounsfield or CT number threshold techniques).

With respect to claim 3, Sabol as modified by Kim, suggest “wherein the second extraction means sequentially searches for a pixel value range usually provided by the non-adipose region, and sets a threshold range of the threshold processing based on the most frequent pixel value in the pixel value range” (Kim: Col. 3, lines 10-14, & 38-67, and Col. 4, lines 1-17, Kim describes using histogram peaks to determine a threshold range, moreover, this range is limited to an are in which non-fat tissue will not be detected, it would be obvious to one of ordinary skill in the art to apply this described feature of Kim to set a threshold range based on pixel frequency in a range provided by the non adipose region, because it would allow for a more dynamic and accommodating detection since fat varies between people).

With respect to claim 4, Sabol as modified by Kim teaches “wherein the second extraction means performs peripheral edge recognition processing of the non-adipose region” (Page 4 & 5 Paragraph 0045, lines 7-11), “sets a plurality of attention points on a recognized peripheral edge” (Page 5, Paragraph 0047, lines 5-19, setting a plurality of points corresponds to Sabol’s delineating the region),

It is however noted that Sabol as modified by Kim fails to explicitly disclose “and interpolates spaces between the plurality of attention points by higher order spline interpolation to extract an outline of the non-adipose region”, as claimed.

On the other hand Sabol states on Page 5, Paragraph 0047, lines 5-19 that a region of interest is delineated manually or automatically, moreover utilizing a higher order spline interpolation for outlining an imaged object is well known in that art as admitted applicant on Page 3, lines 28-29 of “Amendments to the specification”. It would be obvious to one of ordinary skill in the art to implement a well known in the art higher order spline interpolation technique because it would provide a sufficient delineation technique while also achieving a small interpolation error.

With respect to claim 6, Sabol as modified by Kim disclose “wherein the third extraction means extracts the total body adipose region by subtracting the non-adipose region from the body region” (Col. 3, lines 35-38).

With respect to claim 9, Sabol as modified by Kim teach “further comprising an area ratio calculation means which calculates area ratios of the total body adipose region” (Sabol: Page 5, Paragraph 0048, ratio corresponds to Kim’s fat/lean ratio),

“the visceral adipose region, and the subcutaneous adipose region” (Kim: Col. 1, lines 38-46, and See Figure 8),

“wherein the display control means controls to display the area ratios calculated by the area ratio calculation means on the image display device” (Sabol: Page 5, Paragraph 0049).

With respect to claim 10, Sabol as modified by Kim teaches “further comprising a print output means which prints and outputs the tomographic image and the area ratios controlled to be displayed on the image display device by the display control means” (Kim: Figures 2-7, tomographic images are outputted and printed as demonstrated by Kim’s figures).

With respect to claim 11, Sabol discloses “A medical image diagnosing support method” (See Figures 6 and 7),

“comprising: a first extraction step of extracting a body region of a subject from a tomographic image of the subject acquired by a medical tomographic apparatus” (Page 4, Paragraphs, 0043, & 0044, Page 5, Paragraph 0046, lines 1-2, and see Figure 5, extraction step corresponds to Sabol’s characterization);

“a second extraction step of extracting a non-adipose region from the body region” (Page 5, Paragraph 0046, lines 2-7, non-adipose region corresponds to Sabol’s organ such as the liver);

“a third extraction step of extracting a total body adipose region from the body region” (Page 5, Paragraph 0046, lines 7-11, total body adipose region corresponds to Sabol’s fatty tissue); and

“a display control step of controlling of displaying the tomographic image on an image display device” (Page 3, Paragraph 0031, and Page 5, Paragraph 0046, lines 11-23,)

It is however noted that Sabol fails to explicitly disclose “a separation step of separating the total adipose region into a visceral adipose region and a subcutaneous adipose region based on positional information of the non-adipose region”; and

“with clear indication of the visceral adipose region and the subcutaneous adipose region”, as claimed.

On the other hand Kim teaches “a separation step of separating the total adipose region into a visceral adipose region and a subcutaneous adipose region based on positional information of the non-adipose region” (Col. 3, lines 15-31, visceral and subcutaneous adipose regions correspond to Kim's intra-abdominal cavity fat and subcutaneous fat respectively), and

“with clear indication of the visceral adipose region and the subcutaneous adipose region” (Col. 3, lines 18-38, clear indication corresponds to Sabol's high contrast image).

It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to incorporate the teachings of Kim into the system for quantifying tissue fat content of Sabol because both Kim and Sabol are directed to medical image specifically for viewing body tissue (Sabol: abstract; and Kim: Col. 2, lines 10-23), more particularly both are directed segmenting and distinguishing between the types of

imaged body tissue (Sabol: Page 1, Paragraph 0008, also see Figures 5 & 6; and Kim: Abstract) and both are in the same field of endeavor.

Furthermore, incorporate the teachings of Kim into Sabol would have allowed users of Sabol's multi-energy computed tomography method to not only produce an image distinguishing lean and fat tissue (Sabol: Page 1, Paragraph 0007-0008), but also particularly further segment the imaged fat tissue into subcutaneous and intra-abdominal areas as suggested by Kim (Kim: abstract).

Therefore, combination of Sabol and Kim, prior art would have been obvious to one of ordinary skill in the art at the time of invention because to apply the segmentation of subcutaneous and intra-abdominal fat tissue of as taught by Kim, to improve the quantifying fat tissue content CT method as disclosed by Sabol would have yielded the predictable result of improving diagnostic ability by determining and analyzing a subcutaneous to intra-abdominal fat ratio as suggested by Kim (Kim: Page 1, lines 38-46).

With respect to claim 12, claim 12 is rejected on the same basis as the above rejected claim 2.

With respect to claim 13, claim 13 is rejected on the same basis as the above rejected claim 3.

With respect to claim 14, claim 14 is rejected on the same basis as the above rejected claim 4.

With respect to claim 16, claim 16 is rejected on the same basis as the above rejected claim 6.

With respect to claim 19, claim 19 is rejected on the same basis as the above rejected claim 9.

With respect to claim 20, claim 20 is rejected on the same basis as the above rejected claim 10.

10. Claims 5 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sabol et al., U.S. Patent Publication No. 2004/ 0101086 A1, filed on 10/27/2002, Kim et al., U.S. Patent No. 6278761, published on 08/21/2001, and further in view of Grauer et al., Quantification of Body fat Distribution in the Abdomen using Computer Tomography, published in April 1984.

With respect to claim 5, Sabol as modified by Kim teaches “wherein the third extraction means extracts the total body adipose region from the body region” (Page 5, Paragraph 0046, lines 7-11, total body adipose region corresponds to Sabol’s fatty tissue).

It is however noted that both Sabol and Kim fail to explicitly teach "further comprising an epidermal tissue layer removal means which removes an epidermal tissue layer in the non-adipose region", and

"from which the epidermal tissue layer is removed by the epidermal tissue layer removal means", as claimed.

On the other hand Kim states in Col. 3, lines 1-43, and Figures 3-7 that subcutaneous and intra-abdominal fat images are obtained from tomographic scans of a person's abdominal region, which obviously provides "further comprising an epidermal tissue layer removal means which removes an epidermal tissue layer in the non-adipose region", and "from which the epidermal tissue layer is removed by the epidermal tissue layer removal means", because Kim's original tomography image includes materials ranging from air to dense bone with respect to the human body, thus skin is included in this range, furthermore, Kim adjust the Hounsfield value range to distinguish fat from other imaged tissue and bodily material, therefore skin is included in Kim's distinguishing between fat and non fat regions. Furthermore see Grauer Page 632, Col. 1, lines 3-8, and Figure 1, epidermal tissue corresponds to Grauer skin among other non-fat regions distinguished between.

With respect to claim 15, claim 15 is rejected on the same basis as the above rejected claim 5.

11. Claims 7, 8, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sabol et al., U.S. Patent Publication No. 2004/ 0101086 A1, filed on 10/27/2002, Kim et al., U.S. Patent No. 6278761, published on 08/21/2001, and further in view of Wollenweber, US Patent No. 7155047 B2, filed on 12/20/2002.

With respect to claim 7, Sabol as modified by Kim teach “body adipose measurement”

It is noted that both Sabol and Kim fail to teach “further comprising a determination means which determines whether the tomographic image is suitable for”, and

“wherein the display control means controls to display a determination result by the determination means on the image display device”, as claimed.

On the other hand Wollenweber teaches “further comprising a determination means which determines whether the tomographic image is suitable for” (Col. 7, lines 5-34, & 54-62, and Figure 2, item 68, determination of suitable image corresponds to Wollenweber's thresholding to determine images with quality problems);

“wherein the display control means controls to display a determination result by the determination means on the image display device” (Col. 7, lines 47-53 determination result corresponds to Wollenweber's peaks exceeding thresholds).

It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to incorporate the teachings of Wollenweber into the system for quantifying tissue fat content of Sabol as modified by Kim because all, Wollenweber, Kim, and Sabol, are directed to medical imaging (Wollenweber: Col. 1, lines 40-55, and

Figures 1 & 2; Sabol: abstract; and Kim: Col. 2, lines 10-23), more particularly both Wollenweber and Sabol are directed to similar imaging systems and basic techniques (Sabol: Page 2 -3, Paragraph 0029; and Wollenweber: Col. 5, lines 17-39) and both are in the same field of endeavor.

Furthermore, incorporate the teachings of Wollenweber into Sabol as modified by Kim would have allowed users of Sabol's multi-energy computed tomography system to not only produce an image distinguishing lean, subcutaneous, and intra-abdominal fat tissue (Sabol: Page 1, Paragraph 0007-0008; and Kim: abstract), but also assesses the loss of image quality due to lower system sensitivity as clearly suggested by Wollenweber (Wollenweber: Col. 1, lines 6-20).

Therefore, it would have been obvious to one of ordinary skill in the art to use the multiple dataset collection and analyzation of Wollenweber to analyze and threshold the obtained images in Sabol's CT system to determine quality images because Wollenweber further suggest that image quality is inversely proportional to patient size (Wollenweber: Col. 1, lines 21-30), while Sabol's system is directed towards examining, therefore, imaging patients of larger size (Sabol: Page 1, Paragraph 0005 and 0006).

With respect to claim 8, Sabol, and modified by Kim and Wollenweber teach "wherein when the determination means obtains error information that the tomographic image is not obtained from a site suitable for body adipose measurement of the subject or not acquired by a predetermined medical tomographic apparatus, the display control means controls to display the error information on the image display device" (Col. 7,

lines 41-53 error information corresponds to Wollenweber's peaks exceeding thresholds, and Wollenweber's white bar artifacts displayed in erroneous images).

With respect to claim 17, claim 17 is rejected on the same basis as the above rejected claim 7.

With respect to claim 18, claim 18 is rejected on the same basis as the above rejected claim 8.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. Cited Non-Patent literature in PTO-892, line items V, W, and X – art is directed to medical papers that utilized CT imaging systems that distinguished subcutaneous and visceral fat regions of an imaged CT scan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIAN D. BROOKS whose telephone number is (571)270-3951. The examiner can normally be reached on Monday to Thursday EST 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vikkram Bali can be reached on 571-272-7415. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JDB

07/14/2008

/Brian Q Le/
Primary Examiner, Art Unit 2624